

STEPHANIE M. HINDS (CABN 154284)
Acting United States Attorney

HALLIE HOFFMAN (CABN 210020)
Chief, Criminal Division

JEFF SCHENK (CABN 234355)
JOHN C. BOSTIC (CABN 264367)
ROBERT S. LEACH (CABN 196191)
KELLY I. VOLKAR (CABN 301377)
Assistant United States Attorneys

150 Almaden Boulevard, Suite 900
San Jose, California 95113
Telephone: (408) 535-5061
Fax: (408) 535-5066
Kelly.Volkar@usdoj.gov

Attorneys for United States of America

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)	Case No. 18-CR-00258 EJD
)	
Plaintiff,)	UNITED STATES' RESPONSE TO DEFENDANT
)	RAMESH "SUNNY" BALWANI'S MOTIONS
v.)	<i>IN LIMINE</i>
)	
RAMESH "SUNNY" BALWANI,)	Date: January 6, 2022
)	Time: 9:00 a.m.
Defendant.)	Court: Hon. Edward J. Davila
)	

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The government respectfully submits the following omnibus response largely opposing Defendant Ramesh “Sunny” Balwani’s motions *in limine*. ECF No. 1156 (Balwani MILs). Throughout the response, the government references the ongoing trial of co-Defendant Elizabeth Holmes in *United States v. Holmes*, No. 5:18-CR-00258-EJD-1 (“*Holmes* trial”), with which the Court is familiar.

I. OPPOSITION TO DEFENDANT’S MOTION *IN LIMINE* NO. 1 TO EXCLUDE EVIDENCE OF ACCURACY AND RELIABILITY OF TESTS RUN ON UNMODIFIED COMMERCIAL DEVICES

The government opposes Defendant Balwani’s motion *in limine* to exclude evidence related to tests run on unmodified commercial devices (ECF No. 1156 at 12–22), which relies on an overly technical and improper reading of the operative Indictment as it has alleged Defendants’ conspiracy to defraud paying Theranos patients.

The Third Superseding Indictment (“TSI” or “Indictment”) alleges that Defendant Ramesh “Sunny” Balwani and co-Defendant Elizabeth Holmes devised a scheme to defraud patients between approximately 2013—when Theranos began providing lab testing services to patients through certain Walgreens stores in Palo Alto and Arizona—and 2016—when Theranos elected to shutter its lab following interactions with CMS. ECF No. 469 (TSI) ¶¶ 14–18. Specifically, the TSI alleges that from 2013 to 2016, the entire time Theranos was providing testing services to patients, Theranos represented to doctors and patients that Theranos could provide accurate, fast, reliable, and cheap blood tests and test results at the same time that Defendants knew that Theranos was not, in fact, capable of consistently producing accurate and reliable results. *Id.* Based on an order from the Court, the government provided a Bill of Particulars and ultimately incorporated those 25 assays into the TSI for the patient-related counts. *Id.* ¶ 16. The government has amended its Bill of Particulars to add CBC and its component assays. *See* ECF No. 1157 at 83 (Exh. 16).

A. Patient E.T. Should Not Be Precluded from Testifying

Defendant Balwani’s effort to exclude the testimony of patient-victim E.T. is both a motion to reconsider the Court’s evidentiary rulings in the ongoing *Holmes* trial and tantamount to a motion to dismiss Count Ten of the operative Indictment. The Court should deny Defendant’s request because it relies on an overly narrow and hyper-technical reading of the Indictment in this case.

Defendant argues that references in the Indictment to “Theranos’s technology” should be read to

1 restrict the scope of the charges in this case solely to issues with tests performed on Theranos-
 2 manufactured or Theranos-modified devices. Defendants’ scheme to defraud patients was broader than
 3 that, however, and the Indictment puts them on notice of that fact. Indeed, the language of the
 4 Indictment makes this clear by going beyond statements about the abilities of “Theranos’s technology”
 5 and including allegations about Theranos’ abilities as a whole. *See* ECF No. 469 (TSI) ¶¶ 14–18. In
 6 connection with those allegations, the Indictment references assays that were not run on Theranos-
 7 specific technology, explicitly including HIV—the very assay that Theranos conducted for patient-
 8 victim E.T. *Id.* ¶ 16. Specifically, the TSI alleges Defendants Holmes and Balwani engaged in a
 9 scheme to defraud patients who came to Theranos for blood testing services, representing to those
 10 patients that “*Theranos* could provide accurate, fast, reliable, and cheap blood tests and test results”
 11 despite their knowledge that “*Theranos* was not capable of consistently producing accurate and reliable
 12 results for certain blood tests including . . . HIV.” *Id.* ¶¶ 16–17 (emphasis added). Although the
 13 government does not dispute that the relevant sections of the Indictment also make allegations about
 14 problems with “Theranos’s technology,” the Indictment’s use of broader statements—and the explicit
 15 inclusion of assays like HIV not run on Theranos-specific devices—is inconsistent with Defendant’s
 16 argument that the case is limited to those devices. Defendant’s reading of the Indictment places too
 17 much weight on the phrase “Theranos’s technology” and attempts improperly to import that language
 18 into other allegations in the Indictment. Adopting that interpretation would be contrary to Ninth Circuit
 19 guidance that “an indictment is not to be read in a technical manner, but is to be construed according to
 20 common sense with an appreciation of existing realities.” *United States v. Anderson*, 532 F.2d 1218,
 21 1222 (9th Cir.), *cert. denied*, 429 U.S. 839 (1976). Other Circuits are generally in agreement that
 22 “indictments are reviewed on a practical basis and in their entirety, rather than in a hypertechnical
 23 manner.” *United States v. Miller*, 883 F.3d 998, 1002 (7th Cir. 2018) (quotation omitted). In this case,
 24 reading the operative Indictment as a whole demonstrates that E.T.’s testimony is admissible as relevant
 25 to Count Ten and the charged scheme to defraud paying patients overall.

26 Excluding the testimony of E.T. regarding her inaccurate HIV antibody test would be especially
 27 illogical given the evidence presented during the *Holmes* trial regarding Defendants’ shared scheme to
 28 defraud patients. The evidence at trial has shown that Defendants made sweeping statements about the

1 accuracy and reliability of Theranos' tests as a whole. Indeed, Defendants hid from the public (as well
2 as investors) which tests were and were not performed on Theranos' technology, making it impossible
3 for patients purchasing Theranos' services to know on what device their test would be performed.
4 Moreover, they did not merely claim that Theranos' tests were accurate, they caused investors and
5 patients to believe that Theranos' tests were *more* accurate than the conventional tests previously
6 available through competing labs. For example, in September 2013, the *Wall Street Journal* published
7 an article in its editorial pages—after conducting an interview of co-Defendant Holmes and providing
8 her an opportunity to review the content—including the claim that Theranos' testing accuracy
9 represented an “advance” in comparison to conventional tests that suffered from problematic levels of
10 human error. *See United States v. Holmes*, 09/22/2021 Trial Transcript at 1549:7–1552:24 (admitting
11 Trial Exhibit 1106). Claims like that were not limited to individual assays and were designed to attract
12 investors and patients alike. It is readily apparent that claims of superior accuracy were material to
13 patients' decisions to patronize the new lab.

14 The evidence in the *Holmes* trial has also shown that Defendants' claims of superior accuracy
15 were false across the board—including as to the HIV assay. *See, e.g., United States v. Holmes*,
16 11/10/2021 Trial Transcript (“11/10 Tr.”) at 5993:16–5996:11 (describing widespread issues in the
17 “BUGS” or microbiology lab and Dr. Das specifically noted concerns with the HIV assay that may
18 jeopardize patient care). In reality, Theranos' homegrown devices were not even capable of performing
19 an HIV test in the company's clinical lab. This forced Theranos to rely on the same commercially
20 available machines and methods used for HIV tests in other labs and thus made it impossible for the
21 company to deliver on its promise of superior accuracy as to that test. Moreover, trial evidence also has
22 established that Theranos' laboratory used deficient practices in connection with the HIV assay that
23 would have had a detrimental effect on testing accuracy and reliability. *Id.*; *see also* Declaration of
24 Kelly I. Volkar in support of the Government's Response to Defendant Balwani's Motions *In Limine*
25 (“Volkar Decl.”), Exhibit 1.

26 Because E.T.'s inaccurate HIV antibody test result is evidence of Theranos' broken promise to
27 provide patients with tests of superior accuracy and reliability, and because the transmission of those test
28 results was in furtherance of Defendants' scheme to defraud paying patients, the Court should admit

1 E.T.'s testimony against Defendant Balwani as it did against Holmes.

2 **B. Patient B.B. Should Not Be Precluded from Testifying**

3 For similar reasons and others, Defendant's attempt to block testimony from patient-victim B.B.
4 must fail. Even if Defendant could show that all of B.B.'s Theranos tests were run on commercially
5 available machines using FDA-approved methods, the reasoning above would still apply to render his
6 testimony admissible. Because Defendants falsely promised patients that Theranos could deliver test
7 results with superior accuracy in an effort to lure patient customers, inaccurate test results derived from
8 conventional analyzers are evidence that patients did not receive the benefit of the bargain. In the case
9 of B.B.'s results, however, the evidence suggests that Theranos-specific technology *was* used for his
10 CBC panel, contrary to Defendant's representations.

11 As Defendant notes, B.B. is expected to testify that he recalls his first test with Theranos being
12 run on a fingerstick sample. Defendant asserts that B.B.'s fingerstick sample must have been processed
13 on one of two devices: the BD Fortessa or the Drew 3. ECF No. 1156 at 17–18. Defendant concedes
14 that the BD Fortessa would qualify as "Theranos technology" in the context of its argument but argues
15 that the Drew 3 was an unmodified device. Defendant's attached exhibits do not establish that fact.
16 Exhibits 11 and 12 to Defendant's motion are internal Theranos laboratory documents that share an
17 "effective date" of November 14, 2015. *See* ECF No. 1156-2 at 293, 303. It is unclear how probative
18 they are of Theranos' practices in August 2015 when B.B.'s samples were analyzed. To the extent
19 Exhibit 11 can speak to the workflow in the Theranos clinical lab in August, it suggests that the Siemens
20 Advia 2120i and the Drew 3 analyzer were used to conduct *Theranos-specific LDTs*, not standard FDA-
21 approved tests. *See* ECF No. 1156-2 at 295–96. Theranos' Interrogatory Responses from the PFM
22 litigation confirm that the BD Fortessa *and* Drew Scientific Drew-3 were both modified, Theranos-
23 specific devices during the relevant time period. Volkar Decl., Exhibit 2. In those responses, Theranos
24 expressly names those devices in response to a request that they identify any commercially available
25 equipment the company modified to process blood tests on micro-samples. *Id.* Those responses also
26 confirm that those modified devices were in use by Theranos during Summer 2015. *See id.* at PFM-
27 ROGS-00000300 and -304. Thus, the evidence shows that B.B.'s first sample was processed using
28 Theranos-specific technology.

1 Defendant further asserts that, because B.B.'s subsequent tests involved venous samples, they
2 could only have been run on commercially available non-Theranos machines. Assuming B.B.'s
3 recollection is correct that his other Theranos tests were performed on venous samples, however, that
4 still would not establish that they were run on non-Theranos technology. As an initial matter, Defendant
5 mischaracterizes B.B.'s August 27, 2015 lab report as indicating that his test was processed in Theranos'
6 Arizona laboratory, which used only non-Theranos devices. *See* ECF No. 1156 at 17. In fact, the
7 opposite is true: B.B.'s Theranos lab report states on its face that the inaccurate PLT test and all his
8 other assays were "processed at Theranos Laboratories, 7373 Gateway Boulevard, *Newark, CA.*"
9 Volkar Decl., Exhibit 3 (emphasis added). As the Court knows, the Newark, California lab was the
10 location where all of Theranos' company-specific laboratory developed tests, or LDTs, were performed.
11 The fact that B.B.'s August 27 sample was processed in California suggests that it was run on Theranos-
12 specific technology. Indeed, if those CBC tests were run on commercially available devices that could
13 have been operated in Theranos's medium-complexity Arizona lab, there would have been no reason to
14 ship his sample all the way from Phoenix to California for processing.

15 Moreover, there is evidence that, in some cases, Theranos apparently ran venous samples on its
16 proprietary technology by transferring venous blood from larger vacutainers to the company's
17 proprietary CTN containers used exclusively with its proprietary tests. Volkar Decl., Exhibit 4.
18 Theranos may have taken this approach with venous samples of B.B.'s blood in August 2015, which
19 would explain the processing location for his August 27 test.

20 Testimony from B.B. was excluded from the *Holmes* trial after defense counsel raised an
21 objection for the first time during trial that the assay in question—the CBC panel or individual PLT
22 assay—did not appear on the government's Bill of Particulars listing assays the government alleges to
23 be inaccurate. The government promptly corrected this oversight as to Defendant Balwani by providing
24 an Amended Bill of Particulars on November 5, 2021 including the CBC panel and its component
25 assays. *See* ECF No. 1157 at 83 (Exh. 16). That formal notice, in addition to previous notice in the
26 form of interview memoranda and records relating to B.B.'s inaccurate CBC/PLT test, are sufficient to
27 put Defendant on notice regarding the scope of the charges and avoid any risk of prejudice at trial.
28 And, on balance, the evidence supports an inference that one or all of B.B.'s tests were run on Theranos-

specific technology. For those reasons and others as explained above, the Court should deny Defendant's motion to exclude the testimony of this patient-victim.

C. The CMS Form 2567 and Cover Letter Should Not Be Excluded

Defendant Balwani asks this Court to reconsider and reverse its prior ruling related to the same regulatory deficiency report and cover letter—issued by the Centers for Medicare and Medicaid Services' ("CMS") on January 25, 2016 ("CMS Report")—based upon the same arguments made previously by his co-Defendant Holmes. ECF No. 1156 at 20–22. For the same thoroughly vetted reasons the Court granted the government's motion earlier this year, the Court should reach the same conclusion here. *See* ECF No. 798 (Order re: Motions *In Limine* ("MIL Order")) at 16–20, 90; *see also* ECF Nos. 574, 588, 659, 675, 717, 726, 810, 846, 850, 887, 897, 906, 989, 1086, 1133, 1134, 1155 (discussing admissibility of CMS Report and cover letter in co-Defendant Holmes' pretrial proceedings and during her trial).¹ Furthermore, there is no principled bases to limit the government to seeking to admit only the portions it sought admission of during the *Holmes* trial, and the Court should grant the CMS Report's wholesale admissibility as requested in the government's motion *in limine* No. 7. ECF No. 1155 at 14–18.

Defendant Balwani takes issue—as his co-Defendant did before him—with CMS' "immediate jeopardy" finding and seeks to redact all reference to it under Federal Rule of Evidence 403. ECF No. 1156 at 20–22. However, the Court addressed these exact same arguments in co-Defendant Holmes' pretrial proceedings and held that "CMS's finding of 'immediate jeopardy'" did not raise unfair prejudice concerns. ECF No. 798 (MIL Order) at 19. Nevertheless, a few weeks before her trial began, co-Defendant moved the Court to reconsider its finding on the January 2016 CMS Report—based again on relevance and hearsay grounds—and asserted that the Court's prior ruling did not encompass the CMS cover letter accompanying Form CMS-2567. ECF Nos. 897, 906. The Court disagreed, holding

¹ In response to Defendant adopting co-Defendant Holmes' relevant filings on this topic (ECF No. 1156 at 20 n.3), the government incorporates by reference its oppositions and briefs on the topic, including all supporting memoranda of points and authorities, declarations, attachments, other supporting evidence, and any oral arguments made in connection with the filings. *See, e.g.*, ECF Nos. 588, 675, 726, 906, 1133. The government also incorporates by reference its motion *in limine* to admit the CMS Report and accompanying cover letter filed in this case. ECF No. 1155 at 14–18.

that “no new arguments have been presented to justify the breadth of the redactions requested” by co-Defendant Holmes and “reject[ing] Holmes’s assertions that the cover letter is ‘new’ and not covered in the MIL Order.” ECF No. 989 at 7–8 & n.1 (Order re: Pre-Trial Motions (“MIL Order 2”)). Defendant Balwani does not provide any reason to depart from the Court’s prior ruling in his case.

The Court should also reject Defendant Balwani’s motion to redact portions of the CMS Report because he incorrectly asserts those portions are outside the scope of allegations included in the TSI. *Cf.* ECF No. 1156 at 20–22. The Indictment alleges that Defendant Balwani “knew that Theranos was not capable of consistently producing accurate and reliable results for certain blood tests, including but not limited to . . . PT/INR[.]” ECF No. 469 (TSI) ¶ 16. The Indictment continues: “Despite their knowledge of Theranos’s accuracy and reliability problems, HOLMES and BALWANI used interstate electronic wires to purchase advertisements intended to induce individuals to purchase Theranos blood tests at Walgreens stores in California and Arizona” and specifically alleges that Defendant Balwani “held Theranos’s blood tests out to individuals as accurate and reliable.” *Id.* ¶ 17.

Defendants’ interactions with CMS and the resulting CMS Report they receive relate directly to these allegations in the Indictment. Beginning in September 2015, CMS surveyors Sarah Bennett and Gary Yamamoto conducted an in-person inspection of Theranos’ Newark, California laboratory and observed that Theranos’ blood analyzer repeatedly failed quality control checks and repeatedly produced values outside of ranges *Theranos* deemed acceptable—yet Theranos continued to report patient results. *See* ECF No. 675 at 5–10. Bennett told the government in an interview that “Sunny Balwani was the ‘in charge’ person” during the inspection. Volkar Decl., Exhibit 5 at 2. Bennett also told the government that CMS informed Theranos at the end of its survey that it was considering the “immediate jeopardy” finding and Defendants Balwani and Holmes tried to negotiate with CMS not to reach that finding. *See id.* Indeed, Bennett specifically called attention to the issues she observed with respect to PT/INR because if Theranos “[did not] investigate problems of PT/INR, it could keep a systemic error hidden and it would be impossible to know if patients were affected.” Volkar Decl., Exhibit 6 at 6. Indeed, Bennett concluded: “There is a systemic issue of quality. Across the board, not just with the Edison but also their other testing.” *Id.* at 7. Nevertheless, Theranos continued to offer its blood testing services to patients after September 2015, even though, as Defendant asserts, the deficiencies CMS uncovered went

beyond Theranos' proprietary blood analyzer device. *See, e.g., id.* at 4.

CMS ultimately memorialized its findings in the January 2016 CMS Report. *See* ECF No. 675 at 5–10. On information and belief from the government's interviews of Sarah Bennett, CMS reports often make findings in the context of an individual assay, even though those identified deficiencies may have also been present with respect to other assays at Theranos, which is what led Bennett to suspect "systemic error[s]" in Theranos' laboratory. *Id.* at 4–7. Bennett informed the government during her interview that "[a]ll these CLIA requirements are a means to make sure patient results are accurate and reliable" and Bennett, on behalf of CMS, determined that "Theranos didn't meet the regulatory requirements[.]" *Id.* Thus, the CMS Report and cover letter are directly relevant to allegations in the Indictment, particularly with respect to the conspiracy to defraud paying Theranos patients during the period of 2013 to 2016. At the very least, the CMS Report and cover letter are admissible in their entirety for the purpose of notice to Defendant Balwani that Theranos' blood testing services may have been generating inaccurate and unreliable test results, at a time when the CLIA laboratory was still processing patient blood samples.

For these reasons as well as the government's prior arguments on this same topic, the Court should admit the January 2016 CMS Report and accompanying cover letter, and permit paying Theranos patients B.B. and E.T. to testify at Defendant Balwani's trial.

II. OPPOSITION TO DEFENDANT'S MOTION *IN LIMINE* NO. 2 TO EXCLUDE EXPERT TESTIMONY OF DR. KINGSHUK DAS

Defendant seeks to exclude Dr. Kingshuk Das as an expert witness for the same exact reasons raised by co-Defendant Holmes and rejected by the Court in her trial, with purported additional support regarding accessibility of the LIS database. ECF No. 1156 at 23–30. The Court should deny Defendant Balwani's motion for the same reasons it denied co-Defendant Holmes' identical pretrial motion—Dr. Das is a percipient witness the government may call to testify to describe what he observed while performing the job Defendants hired him to do, namely, respond to the CMS deficiency findings. ECF No. 989 (MIL Order 2) at 3–4; *see also* ECF Nos. 906, 1133;² *see generally United States v. Holmes*,

² In response to Defendant adopting co-Defendant Holmes' relevant filings on this topic, the government incorporates by reference its oppositions and briefs on the topic, including all supporting memoranda of U.S. RESPONSE TO BALWANI'S MOTIONS *IN LIMINE*,
CASE NO. 18-258 EJD

11/09/2021 Trial Transcript (“11/9 Tr.”) (holding oral arguments at outset of trial day regarding Dr. Das as an expert among other issues and co-Defendant Holmes’ counsel raising Rule 702 objections periodically during Dr. Das’ testimony).

A. The Substance of Dr. Das’s Testimony is Percipient Not Expert Testimony

The government and co-Defendant Holmes extensively discussed with the Court whether Dr. Das’ expected testimony should be considered percipient or expert testimony under Federal Rule of Evidence 702. *See, e.g.*, ECF Nos. 892, 906, 912, 926, 989, 1133, 1134; 11/9 Tr. at 5684:15–5688:19, 5693:8–5695:25. The Court largely agreed with the government that, based on the government’s representations at the August 20, 2021 hearing, “the Court is persuaded that Dr. Das may proceed as a percipient witness.” ECF No. 989 (MIL Order 2) at 4. The Court warned, however, that discussion of “the Six Sigma analysis [] would move Dr. Das’s testimony from percipient to expert.” *Id.* The Court’s ruling in its MIL Order 2 matches the discussion at the hearing, where the Court expressed reservation about the Six Sigma analysis, but noted it was possible for the witness to testify in a percipient manner and not get into those specifics, providing the following hypothetical: “This is my job, this is what I do, I get the results, I look at the results, . . . I compare it to whatever it is, and that’s not my opinion, it’s the results, and I’m reporting the results [to my boss].” 08/20/2021 Hearing Transcript at 64:18–80:25; *see also United States v. Chen*, No. 17-CR-00603-BLF-1, 2021 WL 2662116, at *9–10 (N.D. Cal. June 29, 2021) (rejecting similar contention by defendant that engineers employed by company in trade secret case should be deemed experts rather than permitted to testify as lay witnesses). Co-Defendant Holmes expressed her view that only 20% or less of Dr. Das’ testimony would qualify as percipient testimony, but the Court disagreed. *Id.* The Court also noted that it provided its thoughts on what testimony—in particular the Six Sigma analysis—would cross the line into expert testimony and the government would proceed into such topics at its own peril. *Id.* at 79:19–80:18. Dr. Das ultimately testified during the *Holmes* trial, and the Court largely overruled co-Defendant Holmes’ Rule 702 objections in keeping with its prior Order. *See* 11/9 Tr. at 5780:12–5861:10.

Defendant Balwani does not raise any new arguments with respect to why Dr. Das’ testimony

points and authorities, declarations, attachments, other supporting evidence, and any oral arguments made in connection with the filings.

1 should be considered expert testimony, Defendant merely disagrees with the Court’s prior ruling. *See*
 2 ECF No. 1156 at 23–30. Defendant cites the same legal authority in support as did his co-Defendant.
 3 *Compare id.* at 25, *with* ECF No. 892 at 6. But the Court has routinely held, and properly so, that
 4 witnesses called to testify about their jobs—what Defendants hired them to do—and what they observed
 5 while performing those duties are merely fact witnesses describing their percipient observations. *See*
 6 ECF Nos. 798 (MIL Order) at 70–72, 75–78 (rejecting co-Defendant Holmes’ similar categorization of
 7 former Theranos lab director Dr. Adam Rosendorff’s testimony as expert testimony), 989 (MIL Order 2)
 8 at 3–4 (holding Dr. Das’ proffered testimony largely percipient except for testimony regarding the
 9 Six Sigma analysis). The portions of Dr. Das’ testimony in the *Holmes* trial that Defendant Balwani
 10 cites (ECF No. 1156 at 24) were admitted either without objection or over objection, and Dr. Das
 11 described more technical aspects such as the Sigma metric in response to questions on cross examination
 12 rather than in response to the government’s questions. *See, e.g.*, 11/10 Tr. at 5941:2–5942:13.

13 The facts to which Dr. Das would be called to testify in Defendant’s trial support the Court’s
 14 prior finding that his testimony is largely percipient. Dr. Das was hired by Defendants Holmes and
 15 Balwani as Theranos’ Newark Lab Director in large part to respond to questions from CMS connected
 16 with the agency’s inspection of Theranos’ Newark laboratory. ECF No. 727-2 at 2. Within the scope of
 17 his duties as lab director, and while attempting to respond to CMS as he was hired for his expertise to
 18 do, Dr. Das observed concerns with certain lab practices—in particular with Theranos’ proprietary blood
 19 analyzer device (called the “Edison” or “TSPU” or 3.0 or 3.5)—and communicated those concerns to
 20 Defendants Holmes and Balwani. *See* ECF Nos. 727-2, 846-2. At its core, that is fact witness
 21 testimony. Indeed, Dr. Das’s proposed testimony about the accuracy and reliability of Theranos’ Edison
 22 assays as he was working on responding to the CMS audit and resulting questions falls into the same
 23 category already ruled upon by the Court—fact testimony that may involve an explanation of his
 24 professional judgment as a lab director. *See* ECF Nos. 798 (MIL Order) at 47–54, 70–72, 75–78, & 989
 25 (MIL Order 2). As the Court previously found, the government should be permitted to call Dr. Das to
 26 testify about his job, what he was hired by Defendant to do, what he discovered in performing the tasks
 27 the Defendants asked him to do (namely, investigate CMS’s findings and concerns), and his perspective
 28 of the resulting discussion of what he discovered with senior management. Each of those topics are

1 squarely within his percipient knowledge.

2 **B. Dr. Das Did Not Rely Directly on Theranos' LIS and Its Inaccessibility Is Not a**
 3 **Reason to Preclude Dr. Das from Testifying**

4 Because Dr. Das would testify as a percipient, rather than expert, witness if called during
 5 Defendant Balwani's trial, "the introduction of a scientific basis and methodology pursuant to Rule 702
 6 is not needed." ECF No. 798 (MIL Order) at 77. Contrary to Defendant's arguments and authority that
 7 he is entitled to the bases for an *expert's* opinion, the information a percipient witness relied upon to
 8 inform his or her judgment in the moment is not something to which a defendant is entitled. *Contra*
 9 ECF No. 1156 at 25–26, 27–30. As a hypothetical example, if the Chief Financial Officer maintains a
 10 company's balance sheet and tallies the company's incoming revenue every month based upon customer
 11 receipts, and the monthly expenses based on the company's received invoices, she would be permitted to
 12 testify at trial about the state of the company's financial health at any given point based upon her
 13 personal knowledge of preparing those balance sheets even if the underlying customer receipts or
 14 monthly invoices have long since been destroyed by the company. A fact witness may testify to
 15 percipient events to which he or she has personal knowledge, even if defense counsel cannot later
 16 reconstruct the basis for that person's real-time conclusions.

17 Furthermore, Defendant asserts, without substantiated basis, that all data upon which Dr. Das
 18 relied must have come from the LIS database. *See* ECF No. 1156 at 25–26. Co-Defendant Holmes
 19 tested this assumption during cross examination by asking Dr. Das whether he "asked someone to
 20 extract all of th[e] information [he relied upon] out of the LIS, or laboratory information systems,
 21 database" and Dr. Das responded that he was "not sure where they would have extracted [the data]
 22 from" but confirming he did ask for data with respect to all of the assays on Theranos' Edison device.
 23 11/10 Tr. at 5932:4–5933:17. Additionally, Dr. Das described several sources of data upon which he
 24 relied in reaching his conclusions, not all of which would have come from the LIS database. *See* 11/9
 25 Tr. at 5833:20–5834:8 (describing review of validation reports, QC data, and patient test results).

26 Nevertheless, Defendant asserts—as his co-Defendant did previously—that he cannot
 27 sufficiently cross-examine Dr. Das because Defendant does not have access to the same LIS data that
 28 Dr. Das would have been relying on at the time he formed his conclusions. ECF No. 1156 at 27–30.

Defendant again laments the loss of the LIS database—that Theranos dismantled before providing the government with a working copy—because he cannot now, in present day, use that data to reconstruct some other, purportedly rosier picture than what the lab directors such as Dr. Das viewed at the time with the relevant data in front of them, while performing the duties that Defendants Holmes and Balwani hired them to do. But this Court held that “the potential usefulness of the LIS data is speculative” and not necessarily exculpatory. *See* ECF No. 887 at 8–15. Moreover, even if Defendant could access the underlying data and could locate an expert willing to opine today that Dr. Das’s interpretation is incorrect (in which case Defendant has not disclosed such an expert), it still would not change the fact that Dr. Das reached his conclusions *years ago*, while employed by Defendant at Theranos for the purpose of reviewing the data as he did. Access to the documentary bases for Dr. Das’s conclusions will not change his overall testimony—which confirms that his expected testimony is quintessential percipient fact witness testimony rather than expert testimony.

Ultimately, Defendant takes umbrage, as his co-Defendant did previously, with the fact that every lab director who worked at Theranos during the relevant time period—who was provided access to relevant data—had serious concerns with the accuracy and reliability of Theranos’ technology and did not think it should be used to process patient blood samples. But that does not give Defendant the right to try now to challenge the qualifications and methodologies of the people *he* hired to do the job at the time. Furthermore, when the lab directors raised concerns to the executive level of the company, they were dismissed or contradicted without support. *See* ECF No. 727-2. If support existed in the moment to undermine the conclusions of lab directors like Dr. Das, then it would exist elsewhere in the voluminous discovery produced in this case and prior related litigation and investigations, or other witnesses would be willing to testify to that effect. And Dr. Das identified where the files that supported his conclusions reside—left firmly within Theranos’ control. ECF Nos. 727-2 at 4, 846-2 at 3. Thus, Defendant should have all he needs to cross-examine Dr. Das on his percipient testimony, even if it is based on his background and expertise.

C. The Government Accurately Described Theranos’ Decommissioning of the LIS Database Mere Days After Providing the Government an Inaccessible Copy

Defendant’s motion also seeks to relitigate the loss of Theranos’ LIS database—a trove of data

1 that was subpoenaed by the government but never provided in any usable form by Theranos. *See* ECF
2 No. 887 (Order Denying Motion to Suppress (“LIS Order”)). The Court should disregard Defendant’s
3 speculative and irrelevant arguments on this topic and adopt its prior ruling.

4 The Court has received extensive information from the parties in this case regarding the LIS
5 database and its destruction. *See, e.g.*, ECF Nos. 561, 575, 660, 677, 810, 846, 866, 887, 892, 906. In
6 particular, the government has briefed this issue for the Court and submitted relevant evidence in
7 previous filings relating to Defendant Holmes’s motions *in limine* as well as her motion to suppress
8 evidence—both of which sought to limit the government’s ability to present evidence of inaccurate
9 Theranos test results. *See, e.g.*, ECF Nos. 682, 681-36, 846.³ The government incorporates that
10 argument and evidence by reference here.

11 Defendant now re-raises the question of who bears fault for the loss of the Theranos LIS
12 database, suggesting to the Court that the government mishandled collection of the evidence and that the
13 testimony of Dr. Das should be limited as a result. Defendant’s central assertion is that the government
14 might have been able to recover the information contained in the Theranos LIS had it obtained the
15 original hardware that Theranos had used to run the system. ECF No. 1156 at 26–27. As the Court
16 knows, Theranos disassembled this hardware days after providing the government with what it
17 represented was a copy of the LIS data. *See* ECF No. 887 (LIS Order) at 5, 11–15. The evidence
18 previously submitted to the Court shows that Theranos knew the government would be unable to access
19 the data it had provided but did not inform the government of that fact. Instead, the government was led
20 to believe that it had a viable copy of all the information stored in the LIS, obviating any need to obtain
21 the original copy of the database or seek additional hardware. Accordingly, Defendant’s argument that
22 the government should have taken additional steps to obtain the LIS database fails. *See id.* at 13–14
23 (rejecting similar arguments made by co-Defendant Holmes). Theranos’ actions in providing what
24 purported to be a complete copy of the LIS caused the government to believe that no additional
25 collection was necessary.

26
27 ³ In response to Defendant adopting co-Defendant Holmes’ relevant filings on this topic, the government
28 incorporates by reference its oppositions and briefs on the topic, including all supporting memoranda of
points and authorities, declarations, attachments, other supporting evidence, and any oral arguments
made in connection with the filings.

By the time the government realized that the copy of the LIS could never be accessed, it was apparently too late. Defendant's argument to the contrary is speculative. While his motion asserts that the original disk drives containing the LIS data "were also stored" (ECF No. 1156 at 26), the record is unclear as to where that data was kept, how long it was retained, or when it ultimately went missing. Nor does it explain why Theranos did not produce that material in response to the government's repeated requests. Defendant should not benefit from that uncertainty when it was Theranos itself that created the confusion around the need to obtain that data.

Ultimately, the evidence already in the record demonstrates that the fault for the loss of the LIS rests with Theranos, not the government. *See generally* ECF No. 887 (LIS Order). Under those circumstances, and for the reasons discussed above, the Court should reject Defendant's attempt to limit the testimony of Dr. Das.

III. OPPOSITION TO DEFENDANT'S MOTION *IN LIMINE* NO. 3 TO EXCLUDE EVIDENCE OF THERANOS VOIDING TEST RESULTS

The Court properly determined that Federal Rule of Evidence 407 governing remedial measures was inapplicable here where Theranos did not voluntarily void all test results run on its proprietary analyzer in the face of regulatory sanctions. *See* 11/9 Tr. at 5827:2–5833:22; ECF No. 798 (MIL Order) at 31–39; *contra* ECF No. 1156 at 31–40. The Court did so after extensive briefing and argument in the *Holmes* matter. *See, e.g.*, ECF Nos. 572, 673, 715, 1133, 1134, 1136; 11/9 Tr. at 5688:20–5692:18, 5697:17–5699:9, 5701:13–5702:6, 5706:16–5708:13, 5824:17–5827:16.⁴ Defendant Balwani raises essentially the same arguments, and the government urges the Court to adopt its ruling with respect to Defendant Balwani's upcoming trial. Defendant Balwani asserts that the CMS surveyors—Sarah Bennett and Gary Yamamoto—controlled the decision of whether Theranos was required to void all tests run on its proprietary analyzer and that the company's decision to void the tests is not sufficiently connected to him. Both assertions are incorrect.

⁴ In response to Defendant adopting co-Defendant Holmes' relevant filings on this topic, the government incorporates by reference its oppositions and briefs on the topic, including all supporting memoranda of points and authorities, declarations, attachments, other supporting evidence, and any oral arguments made in connection with the filings.

1 As the Court previously determined, “[t]he purpose of Rule 407 is to encourage parties to
2 improve safety conditions without fear that subsequent measures will be used as evidence against them[,
3 however,] [a]n exception to Rule 407 is recognized for evidence of remedial action mandated by
4 superior governmental authority . . . because the policy goal of encouraging remediation would not
5 necessarily be furthered by exclusion of such evidence.” ECF No. 798 (MIL Order) at 34 (internal
6 quotation and citations omitted). Theranos was mandated by CMS to “fix” the deficiencies they found
7 during their fall 2015 inspection, which were reported officially in the January 2016 CMS Report, and
8 then the onus was on the laboratory director to determine how to fix it. ECF No. 1157 at 341 (Exh. 36 at
9 6). This is consistent with CMS surveyor Sarah Bennett’s testimony under oath in response to
10 Defendant’s counsel’s questions that “the laboratory director has to determine if and how any patients
11 were affected by the deficient practice” found by CMS because CMS surveyors “do not know . . . if
12 patients were actually affected or not” and, in this particular case, “CMS could never determine the
13 entire universe of patients affected or potentially affected based on the information that [the agency was]
14 provided.” ECF No. 1157 at 332 (Exh. 35). But Bennett was clear that once “the surveyor has
15 identified a deficiency and the laboratory has identified patients affected” then CMS “expect[s] the
16 laboratory to take corrective action” such as “notify[ing] the patient that there may have been a problem
17 with a test[] and that they need to have it retested[.]” *Id.* at 332–33. However, [i]t’s the laboratory and
18 the laboratory director’s responsibility to determine how those patients were affected or have been
19 affected by the deficient practice and what they believe the corrective action should be” and, indeed,
20 Bennett asserted that she could not “speak to what corrective actions laboratory takes because that’s
21 their determination[.]” *Id.* at 332. CMS surveyor Gary Yamamoto’s under oath testimony is consistent.
22 ECF No. 1157 at 328 (Exh. 34). Specifically, he testified that voiding tests was an “unusual remediation
23 for deficient practices” because “generally [the agency] would see laboratories contacting their clients
24 and - - to let them know that there may have been issues with their test [] results during that period of
25 time and that they may want to get retested.” *Id.*

26 The prior testimony of CMS surveyors and the testimony of Dr. Kingshuk Das during the
27 *Holmes* trial is all consistent with the exception to Rule 407: CMS, a federal regulatory agency,
28 mandated that Theranos “fix” the deficiencies it uncovered, including by determining the universe of

1 patients impacted by the deficiencies, and then the onus was on the laboratory director (at the time,
 2 Dr. Das) to determine the proper remediation. *See* ECF No. 1157 at 328, 332–33, 341; 11/9 Tr. at
 3 5824:15–5835:14. Under 42 C.F.R. § 493.1291(k), once a laboratory uncovers errors in a patient’s test
 4 results—such as in response to CMS’s requirement to respond to deficiencies—the laboratory “must”
 5 notify the person and issue corrective results. Dr. Das testified that he prepared a patient impact
 6 assessment in response to CMS’s deficiency findings—indeed, he even cited to the “D-tag” numbers
 7 from the CMS Report—which in turn required him to take corrective action under § 493.1291. 11/9 Tr.
 8 at 5824:15–5835:14. However, as lab director, with the responsibility to take corrective action once
 9 CMS found deficiencies, Dr. Das testified he was unable to determine the true “nature and magnitude of
 10 any effect” on patient results impacted. *Id.* And the patients impacted had their blood tested in 2014
 11 and 2015, up to two years before Dr. Das was completing this analysis. As a result, Dr. Das did not
 12 have the ability to notify the person who ordered the test and issue a corrected test as Mr. Yamamoto
 13 stated was “typical[ly]” done in response to CMS’s deficiency findings. *See* ECF No. 1157 at 328. The
 14 only option available to Dr. Das to comply with the regulations and CMS’s mandate to take corrective
 15 action was to void all test results that may have been impacted, namely all test results performed on
 16 Theranos’ proprietary blood analyzer.

17 The evidence thus supports the Court’s ruling in the *Holmes* trial that Theranos’ decision to void
 18 all tests performed on its Edison or 3-series device was involuntary and not a remedial measure under
 19 Rule 407. *See* 11/9 Tr. at 5827:13–16. Defendant’s citation to *Auer* deference and cases discussing that
 20 deference are beside the point and misunderstands the respective roles of CMS surveyors as compared to
 21 laboratories and lab directors. *Cf.* ECF No. 1156 at 31, 34–37. Defendant conflates the fact that CMS
 22 and the governing regulations permit a laboratory to choose among options how best to correct a
 23 deficiency as a remedial measure when CMS and the regulations are mandating that *some* measure be
 24 taken in response or the laboratory risks further adverse action. Indeed, Defendant’s motion itself states
 25 “Theranos decided to take a more aggressive step to try to avoid CMS’s threat of sanctions and wipe the
 26 slate clean”—that does not indicate a “voluntary” action as contemplated by Rule 407. ECF No. 1156 at
 27 32. As the Fifth Circuit found, Rule 407 “is based ‘on a social policy of encouraging people to take, or
 28 at least not discouraging them from taking, steps in furtherance of added safety,’” but “[i]nvoking this

1 policy to justify exclusion here is particularly inappropriate since the estimate was prepared not out of a
2 sense of social responsibility but because the remedial measure was to be required in any event by a
3 superior authority, the National Highway Traffic Safety Administration.” *Rozier v. Ford Motor Co.*,
4 573 F.2d 1332, 1343 (5th Cir. 1978). So too here. CMS required corrective action and Dr. Das
5 determined the only option available to him to comply with CMS’s mandate was to void all tests
6 performed on Theranos’ proprietary blood analyzer in 2014 and 2015.⁵

7 Defendant Balwani also asserts that the government cannot connect Theranos’ decision to void
8 test results to him because he was asked to resign by co-Defendant Holmes in late April / early May
9 2016. ECF No. 1156 at 38–39. But many of the connections to Holmes also apply to Balwani. First
10 and foremost, Defendant Balwani incorrectly refers only to the conspiracy to defraud investors when
11 setting forth the relevant time period. *See id.* The Indictment alleges that Defendants Balwani and
12 Holmes devised a scheme to defraud patients during the period of 2013 and 2016—when Theranos
13 elected to shutter its lab following interactions with CMS. ECF No. 469 (TSI) ¶¶ 14–18. Specifically,
14 the TSI alleges that from 2013 to 2016, the entire time Theranos was providing testing services to
15 patients, Theranos represented to doctors and patients that Theranos could provide accurate, fast,
16 reliable, and cheap blood tests and test results at the same time that Defendants knew that Theranos was
17 not, in fact, capable of consistently producing accurate and reliable results. *Id.*

18 Second, Defendant Balwani was also involved in hiring Dr. Das to respond to the negative
19 findings of the CMS inspection and CMS Report. As stated during witness interviews, Dr. Das was
20 hired in winter 2015 / spring 2016 as Theranos’s Newark Lab Director by Defendants Holmes and
21 Balwani in part to respond to questions from CMS. ECF No. 727-2 at 2 (memorandum of interview of
22 Dr. Das on February 1, 2021). He worked as a contractor and then full-time employee at Theranos from
23 December 2015 until he was laid off in June 2018. *Id.* Dr. Das also stated that, while employed as
24 Theranos’s Lab Director, he “conducted a Six Sigma analysis of the Edison data and concluded the
25 Edison devices did not perform well, and the accuracy and precision did not meet the level needed for
26

27 ⁵ Defendant also re-asserts as a basis for exclusion the purported fact that Dr. Das relied on the LIS
28 database in reaching his conclusion to void Theranos test results. ECF No. 1156 at 37–38. This
rationale fails for the reasons described above with respect to the motion to exclude Dr. Das’ testimony.

clinical testing.” *Id.* at 3. Indeed, he stated that “even using a fairly low bar, none of the Edison tests passed an acceptable level.” *Id.* Indeed, Dr. Das said that his “Six Sigma analysis led to an uncomfortable meeting setup by Boies Shiller Flexner (BSF) attorneys with HOLMES, BALWANI, and YOUNG” and that this meeting took place after Theranos’ first response to CMS in February 2016 but before the company’s second response. *Id.* Dr. Das said during the government’s interview that he attempted to raise these concerns with Defendants Holmes and Balwani, but received “some push back” and was told this was a “quality systems issue” and “not a device issue[.]” *Id.* Dr. Das disagreed and decided to void all of the Edison test results. *Id.* Dr. Das told the government in his second interview that he and his team “concluded [CMS inspectors] were ‘100%’ correct with their deficiency findings.” ECF No. 846-2 (memorandum of interview of Dr. Das on June 7, 2021). Dr. Das testified at trial that he determined Theranos’ “instruments to be unsuitable for clinical use.” 11/9 Tr. at 5835:5–14.

While Dr. Das met more frequently with co-Defendant Holmes than directly with Defendant Balwani, Defendant was part of the team that hired Dr. Das to conduct the analysis that ultimately led to Theranos voiding test results. In addition, Defendant managed the CLIA lab during the charged conspiracy to defraud patients and thus Dr. Das’ findings relate to the state of that CLIA lab during a relevant time period. Finally, Defendant continued to be Theranos’ Chief Operating Officer (“COO”) and President until approximately May 11, 2016. *See* ECF No. 1150-1; 11/9 Tr. at 8086:7–10 (co-Defendant Holmes asked Defendant Balwani to leave the company). Theranos voided all test results around late March 2016. *See, e.g.*, 11/9 Tr. at 5833:11–5834:12.

In sum, Defendant Balwani’s argument do not warrant the Court reversing course and excluding evidence of Theranos voiding test results, and the government urges the Court to adopt its ruling from the *Holmes* trial based on very similar and overlapping evidence.

IV. OPPOSITION TO DEFENDANT’S MOTION *IN LIMINE* NO. 4 TO EXCLUDE COCONSPIRATOR STATEMENTS

Defendant Balwani seeks to exclude any potential coconspirator statements from before September 2009 or after July 7, 2016 that the government may offer at his trial pursuant to Federal Rule of Evidence 801(d)(2)(E). ECF No. 1156 at 41–46. Defendant’s motion is premature and unnecessary, and the government requests the Court deny outright or defer ruling on this motion pending how

1 evidence is introduced at trial.

2 In November 2021, more than two months into the *Holmes* trial, the government responded to
3 Defendant's request for advance notice of potential coconspirator statements the government may offer
4 at his trial. ECF No. 1157 at 384–85 (Exh. 41). The government specifically noted that, as Defendant's
5 counsel has undoubtedly observed as they have attended the *Holmes* trial, the vast majority of exhibits
6 admitted in the *Holmes* trial to date have been admissible as business records, statements of agents, or
7 for other non-hearsay purposes. *Id.* On occasion, the government has offered Rule 801(d)(2)(E) as a
8 potential basis for admission, but the government is unaware of the Court admitting any exhibit or
9 portion of testimony solely on that basis in the *Holmes* trial thus far. As a result, the government
10 indicated to Defendant that it similarly "anticipates that the vast majority of exhibits offered in the
11 *Balwani* trial will be admissible under multiple hearsay exceptions (or for non-hearsay purposes)[.]" *Id.*
12 Therefore, the government submits the Court should defer ruling on this motion until such time as
13 Rule 801(d)(2)(E) is the critical basis for admission or exclusion of certain evidence.

14 The government submits that, if the parties reach that point, the government will be able to
15 demonstrate the existence of a conspiracy between Defendants in Defendant Balwani's trial, as the
16 Court indicated during the *Holmes* trial that "the evidence that has come in does establish at least for
17 evidentiary purposes a *prima facie* case" that the conspiracy existed. *United States v. Holmes*,
18 11/02/2021 Trial Transcript at 5012:21–5014:25. The government provided notice of categories of
19 evidence Rule 801(d)(2)(E) might be an avenue for admissibility and also its anticipation that most
20 exhibits will be admissible under alternative theories as in the *Holmes* case. ECF No. 1157 at 384–85
21 (Exh. 41). The Court need not weigh in further at this juncture, rather the parties can raise potential
22 issues in advance of testimony or evidence being admitted as the parties did in the *Holmes* case.

23 The specific categories of statements Defendant identifies in his motion further support the Court
24 issuing at most a deferred ruling. *See* ECF No. 1156 at 41–46. With respect to statements by co-
25 Defendant Holmes or others made before September 2009, the government expects it will seek to admit
26 such statements for non-hearsay purposes as it has done in the *Holmes* trial. For example, co-Defendant
27 Holmes' statements regarding the state of the technology or company to investors before 2009 are
28 unlikely to be offered for the truth of the matter asserted, but more likely to be offered for the effect on

the investor's state of mind particularly as it relates to later decisions to invest during the charged period. *See generally United States v. Holmes*, 10/22/2021 Trial Transcript ("10/22 Tr.") at 4433:10–4569:2 (testimony of Bryan Tolbert on behalf of investor-victim Hall Group); *United States v. Holmes*, 11/04/2021 Trial Transcript at 5388:20–5556:10 (testimony of Chris Lucas on behalf of investor-victim Black Diamond Ventures); 11/10 Tr. at 6037:5–6101 (testimony of investor-victim Alan Eisenman).

For statements after Defendant leaves Theranos in July 2016, the government agrees that actions of co-Defendant Holmes and Theranos after July 2016 are largely irrelevant and has moved to exclude such evidence on that basis. *See* ECF No. 1155 at 13–14; ECF No. 1157 at 393 (Exh. 44) (Defendant's July 7, 2016 resignation letter). Defendant identifies co-Defendant Holmes' prior sworn testimony before the SEC and Trial Exhibit 3224 (an August 2016 CNN interview of co-Defendant Holmes). ECF No. 1156 at 44–46. Notably, the government has not sought admission of either of these statements in the *Holmes* trial (although Holmes' SEC testimony has been used for impeachment purposes), and the government does not presently intend to seek to admit them in the *Balwani* trial—further demonstrating why an order from the Court would be premature and unnecessary at this time. To the extent the government does seek to introduce these statements, the government anticipates it would offer admission under other hearsay exceptions, for a non-hearsay purpose, or not for the truth of the matter asserted.

In sum, the government submits Defendant's motion is premature, particularly in light of how trial has proceeded in the *Holmes* case, and the government urges the Court to deny outright or simply defer Defendant's request regarding coconspirator statements.

V. OPPOSITION TO DEFENDANT'S MOTION IN LIMINE NO. 5 TO EXCLUDE EXPERT TESTIMONY OFFERED BY LAY WITNESSES

Defendant moves for an order precluding improper expert opinion from lay witnesses. ECF No. 1156 at 47–50. The government does not intend to introduce inadmissible opinions from non-expert witnesses and submits that a blanket pretrial order is unnecessary to enforce this well-established rule. Instead, the Court should rule on specific testimony if and when it is offered by witnesses in trial and should decline to adopt the overly aggressive interpretation of the rule proposed by Defendant. Furthermore, the Court has previously ruled several of the categories identified by Defendant are

1 percipient rather than expert testimony, albeit with respect to another Theranos employee,
2 Dr. Adam Rosendorff. ECF No. 798 (MIL Order) at 75–78.

3 Defendant’s motion focuses primarily on the trial testimony of Erika Cheung, a former Theranos
4 employee who worked in the company’s clinical lab for several months after obtaining a degree in
5 Molecular and Cellular Biology from University of California, Berkeley. Ms. Cheung’s months at
6 Theranos involved extensive, hands-on experience with the company’s Edison analyzer, including
7 running tests on the device and performing quality control evaluations of its ability to deliver accurate
8 results. In that capacity, she encountered routine problems with the Theranos technology and its
9 accuracy that ultimately caused her to resign after raising those concerns to Defendant and other
10 superiors at the company. Contrary to Defendant’s objections, there was a proper foundation laid for
11 Ms. Cheung’s testimony on these topics.

12 For example, Ms. Cheung was permitted to testify about her understanding of the significance of
13 certain tests and events based on her experience working in Theranos’ lab. Questions and answers were
14 formulated to highlight this foundation. *See, e.g., United States v. Holmes*, 09/14/2021 Trial Transcript
15 at 844:8–845:4 (“Q: Do you have an understanding from your time at Theranos of what the Vitamin D
16 test is and why it’s important?”).

17 Much of Ms. Cheung’s testimony involved highlighting problems with the performance of
18 Theranos technology in situations where others at the company—including Defendant himself—
19 recognized the existence of those problems. *See, e.g., id.* at 845:17–846:9 (witness expressing her
20 agreement with Defendant who characterized a quality control failure event as “beyond unacceptable
21 performance”). Ms. Cheung, whose responsibilities included running quality control checks on a routine
22 basis, was qualified to testify regarding problems she directly observed during her time at Theranos.
23 The fact that those problems were frequently documented and commented on by other employees in
24 contemporaneous business record communications only increases the reliability of her testimony on
25 these events.

26 Ms. Cheung was also qualified to recount her observations of how the performance of Theranos’
27 devices compared to the commercially available devices she worked with in the company’s lab. *United*
28 *States v. Holmes*, 09/15/2021 Trial Transcript (“9/15 Tr.”) at 964:15-965:6 (witness explaining her

1 recollection from her time at Theranos that the company's third-party devices had much better quality
2 control performance than the Theranos devices). Such statements are squarely within the bounds of
3 percipient testimony despite the fact that it relates to a technical subject. *See, e.g., Chen*, 2021 WL
4 2662116, at *9–10 (rejecting similar contention by defendant that engineers employed by company in
5 trade secret case should be deemed experts rather than permitted to testify as lay witnesses). The
6 government does not intend to elicit testimony from Ms. Cheung regarding industry standards or the
7 performance of labs other than Theranos.

8 However, based on Ms. Cheung's extensive experience working with Theranos' analyzers, she
9 was well-positioned to provide a description of their overall reliability and performance. This was
10 percipient witness testimony and therefore outside the scope of Rule 702. To the extent it incorporated
11 Ms. Cheung's opinion, it was simple lay opinion testimony. On that same topic, Ms. Cheung also
12 described conversations and meetings in which she participated at Theranos. During those discussions,
13 she perceived that individuals at the top of the company were eager to try and find an alternative
14 explanation for poor QC performance other than the explanation that seemed obvious to her: that the
15 device itself was not working well. 9/15 Tr. at 920:25–923:20 (explaining that, when Ms. Cheung raised
16 concerns with management, she believed that not enough attention was paid to the possibility that there
17 might be problems with the Edison device itself). This is not expert testimony subject to exclusion
18 under Rule 702.

19 In sum, Ms. Cheung's testimony about problems she observed at Theranos are admissible for
20 multiple reasons. That testimony is primarily percipient testimony of the sort the Court has permitted
21 from other witnesses like Dr. Rosendorff and Dr. Das. *See* ECF Nos. 798 (MIL Order) at 70–72, 75–78,
22 & 989 (MIL Order 2) at 3–4. To the extent Ms. Cheung will describe her reactions or the reactions of
23 others to those issues, that testimony is important to show that problems were well-known at Theranos
24 and were recognized by the relevant individuals. Ms. Cheung's view of those problems is also relevant
25 to her decision to raise concerns with Theranos management—including Defendant Balwani himself—
26 before resigning from her position at the company. For these reasons, the Court should permit the
27 testimony of Erika Cheung consistent with its scope during the *Holmes* trial. Any defense objections to
28 particular statements can be raised and handled in the context of specific questions and answers at trial.

Finally, Defendant's motion includes a request that the Court adopt its ruling from the *Holmes* trial barring physician witnesses from attributing inaccurate Theranos test results specifically to "laboratory error." ECF No. 1156 at 50.⁶ The government does not intend to elicit testimony from treating physicians regarding the potential reasons why Theranos test results might have been inaccurate. Instead, as in the *Holmes* trial, their testimony will focus on their ultimate conclusions *that* certain Theranos test results were incorrect—in addition to offering background information necessary to understand the significance of relevant tests. Although Defendant raises a vague objection to this testimony as well, he presents no specific objection to any particular opinion from any particular physician witness. Accordingly, those witnesses should be permitted to discuss conclusions they reached regarding the accuracy of relevant Theranos test results. After all, those conclusions fall squarely within their demonstrated expertise as physicians familiar with reviewing and interpreting those results in the context of other information gained from examination of their patients.

VI. OPPOSITION TO DEFENDANT'S MOTION *IN LIMINE* NO. 6 TO EXCLUDE CERTAIN TEXT MESSAGES

The Court should deny or defer ruling on Defendant's Motion *in Limine* No. 6. In this motion, Defendant seeks to preclude the government from offering a string of text messages in which Defendant Balwani and co-Defendant Holmes discuss their plan to discourage the *Wall Street Journal* from publishing a negative story about Theranos. This text message thread was admitted without objection during the *Holmes* trial. 10/22 Tr. at 4403:15–4404:10.

Defendant asks the Court to issue a pretrial order precluding the admission of this text message thread under Federal Rule of Evidence 403. Specifically, Defendant argues that references within the thread to "sex" and "murder" are unfairly prejudicial. At the same time, Defendant argues that the meaning of these references is unclear. For several reasons, the Court should decline Defendant's invitation to exclude this thread at this stage. First, the *Holmes* trial provided additional context for this tread. In Trial Exhibit 5704, co-Defendant Holmes emails Rupert Murdoch in an effort to encourage Mr. Murdoch to intervene in the *Wall Street Journal's* plan to publish a negative story about Theranos.

⁶ The government, in turn, incorporates by reference its relevant opposition and supporting materials and argument.

1 *United States v. Holmes*, 11/30/2021 Trial Transcript (“11/30 Tr.”) at 7999:6–8003:6. This same topic
 2 is discussed in this text message thread. This thread is relevant to show that Defendant Balwani knew
 3 about (and approved of) co-Defendant Holmes’ plan to contact Rupert Murdoch for the purpose of
 4 killing the *Wall Street Journal*’s impending negative article. Therefore, this thread is relevant
 5 knowledge and intent evidence, demonstrating that Defendant knew about negative information
 6 regarding Theranos, but sought to discourage its dissemination.

7 Additionally, Defendant claims that references to “sex” and “murder” are unfairly prejudicial,
 8 and likely to “confuse, mislead, and inflame the jury.” ECF No. 1156 at 51. From the context of the
 9 thread, it appears those references relate to co-Defendant Holmes’ experiences and not this Defendant.
 10 Therefore, any Rule 403 analysis would more strongly discourage admission of this thread against co-
 11 Defendant Holmes—where it was admitted without objection—than this Defendant. In other words, if
 12 anyone would be unfairly prejudiced by the admission of this thread, it was Holmes, and she chose not
 13 to object to its admission. This Defendant has not articulated a convincing argument supporting the
 14 Rule 403 analysis as applied to him.

15 Finally, two checks remain available to the Court before unfairly prejudicing this Defendant
 16 through the admission of this thread. First, the Court could redact the references to “sex” and “murder.”
 17 While Defendant summarily dismisses this possibility, it, in fact, would allow the jury to hear relevant
 18 evidence regarding this Defendant’s knowledge of the plan to solicit assistance from Mr. Murdoch to
 19 kill a negative story, without admitting the allegedly unfairly prejudicial evidence. While the
 20 government does not concede that redaction is necessary, it is an option the Court should consider at the
 21 time the government seeks to admit this thread. Second, the government agrees to provide advanced
 22 notice to Defendant before it admits this thread. Thus, the Court need not issue a pretrial order
 23 excluding this thread to inoculate the jury against prejudicial evidence.

24 **VII. NON-OPPOSITION TO DEFENDANT’S MOTION *IN LIMINE* NO. 7 TO EXCLUDE**
 25 **EVIDENCE OF DEFENDANT BALWANI’S LICENSE PLATE**

26 After careful consideration of the arguments raised in Defendant Balwani’s motion (ECF No.
 27 1156 at 56–58) and upon further analysis, the government no longer intends to offer evidence of
 28 Defendant Balwani’s use of the phrase “DASKPTL” on his personalized license plate and does not

1 oppose this motion.

2 **VIII. RESPONSE TO DEFENDANT’S MOTION *IN LIMINE* NO. 8: THE COURT SHOULD**
 3 **ADOPT OR RECONSIDER ITS PRIOR RULINGS IN CO-DEFENDANT HOLMES’**
 4 **TRIAL ONLY AS APPROPRIATE WITH RESPECT TO DEFENDANT BALWANI**

5 The parties agree that the Court’s MIL Order (ECF No. 798) in co-Defendant Holmes’ pretrial
 6 proceedings does not automatically apply to Defendant Balwani’s proceedings, such as under a law of
 7 the case theory. *See* ECF Nos. 1154 (“Mr. Balwani is not bound by rulings in Ms. Holmes’ case.”),
 8 1156 at 61 n.21; *United States v. Guy*, 903 F.2d 1240, 1242 (9th Cir. 1990) (holding “law of the case”
 9 does not apply to severed co-defendants but reaching the same well-reasoned result as a prior panel had
 10 with respect to the absent co-defendant). It is also well-settled that the Court “may change its ruling at
 11 trial because testimony may bring facts to the district court’s attention that it did not anticipate at the
 12 time of its initial ruling.” *City of Pomona v. SQM N. Am. Corp.*, 866 F.3d 1060, 1070 (9th Cir. 2017);
 13 *see also* ECF No. 989 (MIL Order 2). Nevertheless, the Court in this case has spent considerable time
 14 and resources reviewing issues raised during co-Defendant Holmes’ severed and preceding trial that
 15 Defendant Balwani seems to agree “overlap[]” with issues likely to arise in his trial. *See* ECF No. 1156
 16 at 59.

17 As stated throughout its motions *in limine* filed in this case, the government respectfully requests
 18 the Court apply its prior rulings in its MIL Order (ECF No. 798) in the *Holmes* case to Defendant
 19 Balwani, when applicable, and only reconsider when evidence specific to Defendant Balwani warrants
 20 such reconsideration. *See* ECF No. 1155. Defendant Balwani expressly states that “he offers no new
 21 arguments” with respect to eleven issues previously briefed by co-Defendant Holmes on which the
 22 Court denied or deferred ruling. *See* ECF No. 1156 at 59–60, 66–73. The government asserts there is
 23 no basis for the Court to reconsider at this time its prior rulings and incorporates by reference its prior
 24 oppositions and arguments on the associated topics.⁷ *See, e.g.*, ECF Nos. 797 (Order re: Dr. Master),
 25 798 (MIL Order), 989 (MIL Order 2); ECF Nos. 661, 662, 665, 666, 668, 670, 671, 672, 674, 677, 682,
 26 906, 1144 (government oppositions to co-Defendant Holmes’ MILs incorporated by Defendant Balwani

27 ⁷ The government also incorporates by reference all supporting memoranda of points and authorities,
 28 declarations, attachments, other supporting evidence, and any oral arguments made in connection with
 the filings.

at ECF No. 1156 at 59–60); *see also* ECF No. 1004 at 6–7 (tying both Defendants to retaliation against Erika Cheung and Tyler Shultz).

With respect to seven issues previously raised and briefed by co-Defendant Holmes that the Court granted in her pretrial proceedings and which Defendant Balwani now seeks to adopt in his own case, the government requests the Court remain open to reconsidering its pretrial ruling with respect to Defendant Balwani subject to how the evidence is used at his trial. *Cf.* ECF No. 1156 at 59, 61–66. The government again incorporates by reference its prior oppositions and arguments on the associated topics.⁸ *See, e.g.*, ECF Nos. 661, 663, 664, 667, 673, 676, 678, 682, 846 (government oppositions to co-Defendant Holmes’ MILs and motion to suppress incorporated by Defendant Balwani at ECF No. 1156 at 59, 61–66). The government submits the following specific responses to these seven issues:

Motion to Exclude Evidence on Wealth, Spending, and Lifestyle: The government maintains its position as stated in its oppositions with respect to co-Defendant Holmes’ motion regarding her wealth, spending, and lifestyle (ECF No. 663) and requests the Court at least adopt its resulting ruling that permits the government to introduce evidence that Defendant received a salary and perks commensurate with other tech company executives. ECF No. 798 (MIL Order) at 6–9. Furthermore, in response to Defendant’s expressed concerns about appealing to class prejudice (ECF No. 1156 at 61–62 (citing ECF No. 798 at 8–9)), the government respectfully requests the Court extend its Order to exclude any evidence of Defendant Balwani’s wealth or financial status before he joined Theranos or outside of his spending associated with his salary and perks received as an executive of Theranos.

Motion to Exclude Evidence of Certain Settlements: The government did not oppose and still does not oppose Defendants’ motion to exclude evidence of the CMS Settlement or the Arizona Settlement, although statements made in negotiation may be admissible, as noted by the Court. ECF No. 798 (MIL Order) at 38–39; *see* ECF No. 1156 at 62. However, the Court has heard additional evidence regarding CMS’s inspection and the internal Theranos response, which led the Court to reject co-Defendant Holmes’ characterization at trial of voiding the tests in response to CMS findings as a

⁸ The government also incorporates by reference all supporting memoranda of points and authorities, declarations, attachments, other supporting evidence, and any oral arguments made in connection with the filings.

remedial measure. *See* ECF No. 798 (MIL Order) at 31–39; 11/9 Tr. at 5827:2–5833:22. As described further above, the government submits the Court should adopt its ruling with respect to Theranos voiding the test results made during co-Defendant Holmes’ trial with respect to Defendant Balwani, as well. *See supra* pgs. 14–18.

Motion to Exclude Certain News Articles: The government maintains its position as stated in its opposition to this motion (ECF Nos. 667, 906), and notes that the Court has now seen what a trial without the six articles Defendant Balwani seeks to exclude will look like considering the government never sought to introduce the excluded articles in the *Holmes* trial. ECF No. 1156 at 63. As the Court undoubtedly noticed, some of the articles excluded, such as the October 16, 2015 *Wall Street Journal* article by John Carreyrou, play a pivotal role in Defendants’ fraud scheme and are the stimulus of responses by Defendants and witnesses likely to testify at trial, including investors, members of Theranos’ Board of Directors, and employees at the company. It may be helpful context to the jury to see the article that causes such a reaction. Thus, the government requests the Court remain open to reconsidering whether to admit some of the previously excluded articles for a limited purpose—such as effect on the readers—as it initially did for the “Blood, Simpler” article. *See* ECF No. 798 (MIL Order) at 39–44.

Motion to Exclude Customer Impact Evidence: The government maintains its position as stated in its oppositions with respect to co-Defendant Holmes’ motion regarding customer impact evidence (ECF No. 676) and asks the Court to at least adopt the same parameters that it set during the *Holmes* trial. *See* ECF No. 798 (MIL Order) at 47–54. Contrary to Defendant Balwani’s assertion (ECF No. 1156 at 64), the government complied with the Court’s MIL Order in the *Holmes* trial, which contemplated that patients or physicians may testify about next steps but not about “emotional, graphic, or otherwise inflammatory” topics. ECF No. 798 (MIL Order) at 51–52. Defendant Balwani’s motion fails to provide a basis to go beyond the Court’s prior Order and exclude the additional categories Defendant identifies from the testimony of Dr. Zachman and Dr. Rosendorff because (1) there is no guarantee that the witnesses will testify in exactly the same manner at both trials and (2) the words and phrases Defendant takes issue with properly fall within the “next steps” category of testimony that the

1 Court permitted. *Contra* ECF No. 1156 at 64. To the extent Defendant believes testimony violates the
2 Court's Order, he may always object in the moment before the jury.

3 *Motion to Exclude Evidence of Alleged Blaming and Vilifying of Competing Companies and*
4 *Journalist:* The government maintains its position as stated in its oppositions with respect to co-
5 Defendant Holmes' motion to exclude chants and other statements made by Defendants during Theranos
6 all-hands meeting (ECF No. 678) and asks the Court to at least adopt the same parameters that it set
7 during the *Holmes* trial. *See* ECF No. 798 (MIL Order) at 68–70. The Court granted co-Defendant's
8 motion with respect to the chants but deferred with respect to Defendants' "statements to Walgreens
9 employees and the all-hands meeting statements." ECF No. 798 (MIL Order) at 70. Defendant Balwani
10 has not presented any reason for the Court to reach a different conclusion here.

11 *Motion to Exclude Evidence of Tests Not Identified in the Bill of Particulars:* The government
12 respectfully requests the Court reconsider its prior ruling regarding tests not identified on the Amended
13 Bill of Particulars, now that the Court has seen how evidence is likely to come in at trial based on its
14 overseeing of the severed and preceding *Holmes* trial. *See* ECF No. 798 (MIL Order) at 78–80. As the
15 Court is undoubtedly aware, the evidence at trial is likely to reference tests beyond those identified in
16 the Amended Bill of Particulars because Defendants and Theranos employees did not treat each
17 individual assay on a one-by-one basis. Rather, internal Theranos emails often involve employees
18 discussing multiple assays or groups of assays and such emails are still probative of the overall state of
19 Theranos' technology and its CLIA lab. As just one example, CMS inspector Sarah Bennett may testify
20 that the issues CMS found and reported as a deficiency with respect to one assay were often present with
21 respect to multiple assays beyond the one listed in the CMS Report. *See e.g.*, Volkar Decl., Exhibit 6 at
22 4–7 ("There is a systemic issue of quality. Across the board, not just with the Edison but also their other
23 testing."). Thus, even references within the January 2016 CMS Report (discussed above) to non-Bill of
24 Particular assays could still be probative as to assays that are contained on the Amended Bill of
25 Particulars.

26 Moreover, the testimony and evidence during the *Holmes* trial demonstrated widespread issues
27 with Theranos' proprietary technology, as well as performance of Theranos' CLIA lab, and Defendants'
28 knowledge of those problems. As but one example, Defendant Balwani repeatedly described significant

1 problems within Theranos' CLIA lab to co-Defendant Holmes through contemporaneous text messages.
 2 *See, e.g.*, 11/30 Tr. at 8045:24–8086:15 (describing text messages, other messages between Defendants,
 3 and surrounding context). In sum, the Court should reconsider its prior ruling excluding evidence
 4 regarding the purported inaccuracy and unreliability of tests not identified in the Amended Bill of
 5 Particulars because it excludes too large of a swath of otherwise relevant evidence. And the Court
 6 certainly should not exclude portions of the January 2016 CMS Report on this basis, given the proffered
 7 statements of CMS inspector Sarah Bennett that portions related to one assay often applied more broadly
 8 to several assays.

9 *Evidence on Fault for the Loss of Theranos' LIS:* As discussed above, Defendant's attempts to
 10 relitigate the issue of fault for the loss of the LIS do not change the analysis on that issue. *See supra*
 11 pgs. 12–14. The government presently does not intend to introduce evidence at the trial of Defendant
 12 Balwani regarding the destruction of the LIS by Theranos. However, the government respectfully
 13 reserves the right to raise this issue again in connection with evidence linking Defendant himself to the
 14 relevant events. If the government is unable or decides not to make that evidentiary showing, the Court
 15 should consider whether to further restrict discussion of the LIS during the *Balwani* trial given it was a
 16 frequent topic of further discussion during the *Holmes* trial. The Court has previously ruled that the
 17 defense might open the door to this evidence by blaming the government for the loss of the LIS. *See,*
 18 *e.g.*, ECF No. 798 (MIL Order) at 56–58. The Court should apply the same reasoning to arguments by
 19 Defendant that accomplish the same thing by implication. The jury in this case will understand that the
 20 government bears the burden of proof. Comments by the defense regarding the government's failure to
 21 present evidence from Theranos' LIS are tantamount to blaming the government for its loss. In light of
 22 the facts of this case, the Court should not permit those arguments without allowing the government the
 23 opportunity to show how the LIS actually went missing.

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1 Finally, the Court should uphold its prior ruling denying co-Defendant Holmes' motion to
 2 suppress due to inaccessibility of the LIS database, for the reasons described above and in that litigation.
 3 ECF Nos. 846, 862, 866, 887; *contra* ECF No. 1156 at 60, 73–74. The government incorporates by
 4 reference its prior opposition to co-Defendant Holmes' motion to suppress, as well as the arguments the
 5 government made during the associated hearing.⁹ *See* ECF Nos. 846, 866. Defendant Balwani has not
 6 asserted any additional arguments that warrant changing the Court's well-reasoned decision with respect
 7 to co-Defendant Holmes.

8
 9 DATED: December 6, 2021

Respectfully submitted,

10 STEPHANIE M. HINDS
 11 Acting United States Attorney

12 /s/ Kelly I. Volkar

13 JEFF SCHENK
 14 JOHN C. BOSTIC
 15 ROBERT S. LEACH
 16 KELLY I. VOLKAR
 17 Assistant United States Attorneys
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